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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,861	06/28/2001	George R. Pettit	12504.370	5645

7590

09/09/2005

FENNEMORE CRAIG  
3003 N. Central Avenue  
Suite 2600  
Phoenix, AZ 85012

EXAMINER

KANTAMNENI, SHOBHA

ART UNIT PAPER NUMBER

1617

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/893,861	PETTIT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 17-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/24/2003</u>  | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

This application was filed on 06/28/2001, and claims benefit of 60/214,844, filed on 06/28/2000.

Claims 17-30 are pending, and examined herein.

Receipt of The information disclosure statement (IDS) submitted on 09/24/2003 is herein acknowledged.

The Amendment received on 04/02/2004, wherein claims 10-16 have been cancelled, and claims 17-30 have been added. The amendment has been entered and found no new matter.

The Amendment received on 04/02/2004, amended specification by correcting the structure of the androstane based compounds. The amendment has been entered and found no new matter.

The Amendment received on 06/03/2004, amended specification by correcting obvious typographical errors. The amendment has been entered and found no new matter.

In view of new ground(S) of rejection set forth below, the rejections made in the previous office action dated 10/02/2002 are herein withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19, 21-23, 25, 29, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "peptide", "amino acid" in the claims 17, and 30 is vague and indefinite, as it is not clear what other compounds this term encompasses, since one of ordinary skill in the art could not ascertain the metes and bounds as to "peptide, and "amino acid." For example, amino acid can be any compound which has an amine and acid groups, which can be natural amino acids or synthetic amino acids etc., and the term "peptide" is any two or more amino acids bonded together. Thus the term "peptide" can include a variety of different compounds with widely varying structural differences obtained by combining different or same amino acid.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18, 19, 21, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mosbach et al. (US 4,460,509, PTO-892).

Mosbach et al. discloses a method of treating gram positive bacterial infection in a mammal comprising administering compounds of formula as represented in instant claims 17 and 30. See column 11, claim 3 wherein the steroid compound is androstane series having a D-ring side chain as shown; when Q4 is NH, the group attached to D ring will have an amide group which reads on instant structure; a steroid compound of the formula in claim 9, wherein R1 maybe alkyl, acyloxy, R2 is H, Q is CONH which reads on instant claims 18-19. It is further disclosed the androstane compounds can be administered parenterally or peroral, in the form of the tablets, capsules, solutions, elixirs etc., as may be determined by the skilled worker. The dosage selected by the skilled worker depends upon the patient to whom the compound is administered as well as the condition. See column 3, lines 30-60.

Thus Mosbach anticipates the instant claims 17, 18, 19, 21, and 30.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosbach et al. as applied to claims 17, 18, 19, 21, and 30 above.

Mosbach is as discussed above.

Mosbach does not specifically teach the amount of androstane compounds administered as between 25 milligrams to about 1 gram/kg body weight.

Mosbach does not specifically teach the gram positive bacteria as selected from group comprising penicillin-resistant, methicillin-resistant and vancomycin-resistant gram positive bacteria.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the steroid compounds of Mosbach to be administered to a patient to treat the bacterial infection in mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of androstane compounds employed, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Encountering drug resistance in the therapeutic setting, the skilled artisan would have been motivated to employ known antimicrobial compounds structurally distinct

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from those compounds penicillin, methicillin, vancomycin which are known antibacterial for which the resistance was observed. Possessing the instant disclosure of Mosbach, the skilled artisan would have expected that the known androstane compounds therein would be useful in treating antibiotic resistant infective micro-organisms with a reasonable expectation of therapeutic success. Note that the penicillin-resistant strains such as *Streptococcus pneumoniae*, *staphylococcus aureus* etc. are known bacterial strains.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mosbach et al. as applied to claims 17, 18, 19, 21, and 30 above, in view of Pettit et al. (Journal of Medicinal Chemistry, Vol.10, pages 145-148, 1967; PTO-1449).

Mosbach is as discussed above.

Mosbach does not teach the particular androstane compound, 3 $\beta$ -acetoxy-17  $\beta$ -(L-prolyl)amino-5 $\alpha$ -androstane.

Pettit et al. discloses the synthesis of steroidal peptides, including 3 $\beta$ -acetoxy-17  $\beta$ -(L-prolyl)amino-5 $\alpha$ -androstane. It also taught that the steroidal peptides as useful for the treatment of hormone-based medical problems. See page 145, structure II d. It is further taught that the steroidal peptides are useful for greatly enhancing the hydrophilic properties of certain steroids. See page 146, right hand column, paragraph 3.

It would have been obvious to a person of ordinary skill in the art at the time of invention to substitute androstane compounds of Mosbach with a androstane peptide compound 3 $\beta$ -acetoxy-17  $\beta$ -(L-prolyl)amino-5 $\alpha$ -androstane for the treatment of gram

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positive infections in a mammal. One of ordinary skill in the art at the time of invention would have been motivated to substitute androstane compounds disclosed by Mosbach with 3 $\beta$ -acetoxy-17  $\beta$ -(L-prolyl)amino-5 $\alpha$ -androstane which contains a prolyl group with the expectation of enhancing the hydrophilic properties of the compound and thus enhancing its water solubility.

Claims 22-23, 24, 26, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosbach et al., in view of Pettit et al. (Journal of Medicinal Chemistry, Vol.10, pages 145-148, 1967) as applied to claim 20 above, and further in view of in view of Coates et al. (US 5,192,742).

Mosbach, and Pettit is as discussed above.

Mosbach does not specifically teach the topical administration of antibacterial androstane compounds.

Coates et al. teach the treatment of bacterial infections in mammal which comprises administering antibacterial compositions. It is taught that the antibacterial compounds can be formulated for administration by any route such as topical. It is further taught that the topical administration is in the form of ointment, creams, lotions, eye ointments, eye drops, ear drops, impregnated dressing etc. See column 4, lines 27-29, 64-68.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer the antibacterial androstane derivatives topically because Coates teaches that antimicrobial compositions can be administered topically.



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One of ordinary skill in the art at the time of invention would have been motivated to administer the claimed antibacterial compositions topically with the expectation of treating bacterial infections, with local effects.

### ***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni  
Patent Examiner  
Art Unit : 1617

  
**SHAOJIA A. JIANG, PH.D.**  
**PRIMARY EXAMINER**